

I. AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

Claim 1. (Currently Amended) A method of reducing the abuse potential of an oral dosage form of an opioid analgesic, comprising

combining an analgesically effective amount of an orally active opioid agonist together with an ~~opioid antagonist~~ naltrexone or a pharmaceutically acceptable salt thereof into an oral dosage form, said ~~opioid agonist/antagonist~~ opioid agonist/naltrexone or pharmaceutically acceptable salt thereof combination being chosen such that the opioid agonist and ~~opioid antagonist~~ the naltrexone or pharmaceutically acceptable salt thereof are only extractable ~~from~~ from the dosage form together, and at least a two-step extraction process is required to separate the opioid antagonist from the ~~opioid agonist~~ naltrexone or pharmaceutically acceptable salt thereof, the amount of ~~opioid antagonist including~~ naltrexone or pharmaceutically acceptable salt thereof included being sufficient to counteract opioid effects if extracted ~~together~~ from the oral dosage form together with the opioid agonist and administered parenterally.

Claim 2. (Currently Amended) The method of claim 1, wherein said combination of said opioid agonist and said ~~opioid antagonist~~ require naltrexone or pharmaceutically acceptable salt thereof are only extractable from the dosage form together, and thereafter must be separated from each other in a separate extraction step.

Claim 3. (Currently Amended) The method of claim 2, wherein both said opioid agonist and said ~~opioid antagonist~~ naltrexone or pharmaceutically acceptable salt thereof are soluble in acid, and must be separated utilizing a high pH solution.

Claim 4. (Cancelled)

Claim 5. (Currently Amended) The method of claim 1, where ~~to~~ the opioid agonist is hydromorphone hydrochloride and the ~~opioid-antagonist~~ naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 6. (Currently Amended) The method of claim 1 where the opioid agonist is oxycodone hydrochloride and the ~~opioid-antagonist~~ naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 7. (Currently Amended) The method of claim 1 where the opioid agonist is morphine sulfate and the ~~opioid-agonist~~ naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 8. (Currently Amended) The method of claim ~~1~~ 3, ~~further comprising incorporating into the dosage form a further ingredient which makes separation of the opioid agonist from the opioid-antagonist more difficult~~ where the opioid agonist is hydrocodone bitartrate and the naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 9. (Currently Amended) The method of claim ~~1~~ 8, ~~wherein said further ingredient is further comprising incorporating into the dosage form a further ingredient selected from the group consisting of gelling agents, waxes, and mixtures thereof, which makes separation of the opioid agonist from the naltrexone or pharmaceutically acceptable salt thereof more difficult.~~

Claims 10-11. (Cancelled)

Claim 12. (New) An oral dosage form comprising:

- (i) an analgesically effective amount of an orally active opioid agonist; and
- (ii) naltrexone or a pharmaceutically acceptable salt thereof;

said opioid agonist and naltrexone or pharmaceutically acceptable salt thereof being chosen such that the opioid agonist and the naltrexone or pharmaceutically acceptable salt thereof are only extractable from the dosage form together, and at least a two-step extraction process is required to separate the opioid antagonist from the naltrexone or pharmaceutically acceptable salt thereof,

the amount of naltrexone or pharmaceutically acceptable salt thereof included being sufficient to counteract opioid effects if extracted from the oral dosage form together with the opioid agonist and administered parenterally.

Claim 13. (New) The oral dosage form of claim 12, wherein the opioid agonist is hydromorphone hydrochloride and the naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 14. (New) The oral dosage form of claim 12, wherein the opioid agonist is oxycodone hydrochloride and the naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 15. (New) The oral dosage form of claim 12, wherein the opioid agonist is morphine sulfate and the naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 16. (New) The oral dosage form of claim 12, wherein the opioid agonist is hydrocodone bitartrate and the naltrexone or pharmaceutically acceptable salt thereof is naltrexone hydrochloride.

Claim 17. (New) The oral dosage form of claim 12, wherein the opioid agonist is hydromorphone hydrochloride and the ratio of said naltrexone to said hydromorphone is from about 0.148:1 to about 1.185:1 by weight.

Claim 18. (New) The oral dosage form of claim 12, wherein the opioid agonist is hydromorphone hydrochloride and the ratio of said naltrexone to said hydromorphone is from about 0.222:1 to about 0.111:1 by weight.

Claim 19. (New) The oral dosage form of claim 12, wherein the opioid agonist is morphine sulfate and the ratio of said naltrexone to said morphine is from about 0.018:1 to about 1.148:1 by weight.

Claim 20. (New) The oral dosage form of claim 12, wherein the opioid agonist is oxycodone hydrochloride and the ratio of said naltrexone to said oxycodone is from about 0.037:1 to about 0.296:1 by weight.

Claim 21. (New) The oral dosage form of claim 12, wherein the opioid agonist is oxycodone hydrochloride and the ratio of said naltrexone to said oxycodone is from about 0.056:1 to about 0.222:1 by weight.

Claim 22. (New) The oral dosage form of claim 12, wherein the opioid agonist is hydrocodone bitartrate and the ratio of said naltrexone to said hydrocodone is from about 0.03:1 to about 0.27:1 by weight.

Claim 23. (New) The oral dosage form of claim 12, further comprising a sustained release carrier, wherein the sustained release carrier provides for a release of said opioid agonist such that the dosage form is suitable for administration on a twice-a-day or a once-a-day basis.